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IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OKLAHOMA

UNITED STATES OF AMERICA,	)	
	)	
Plaintiff,	)	
	)	Case No. 19-CR-58-JED
v.	)	
	)	
GREGORY SINCLAIR CONNOR,	)	
	)	
Defendant.	)	

JURY INSTRUCTIONS

Dated this 22nd day of November, 2019.

JOHN E. DOWDELL, CHIEF JUDGE
UNITED STATES DISTRICT COURT

JURY INSTRUCTION NO. 15

RECEIVING A MISBRANDED DRUG

The defendant is charged in Count Two of the indictment with Receiving a Misbranded Drug in violation of Sections 331(c) and 333(a)(2) of Title 21 of the United States Code. Under these statutes, it is unlawful to receive or cause to be received in interstate commerce any drug that is misbranded, and to deliver or proffer delivery thereof for pay or otherwise with the intent to defraud or mislead.

To find the defendant guilty of this crime, you must be convinced that the government has proved each of the following elements beyond a reasonable doubt:

(1) the defendant received or caused to be received a drug in interstate commerce;

(2) the drug was misbranded;

(3) the defendant then delivered, or proffered delivery of, the misbranded drug for pay or otherwise; and

(4) the defendant acted with the intent to defraud or mislead.

For a defendant to act with the "intent to defraud or mislead," he must have some knowledge that the drugs were misbranded.

A defendant acts with intent to defraud if the defendant acts with the intent to defraud or mislead either (1) the consumers of the defendant's products or (2) the government. You must all agree on whether the defendant acted with the intent to defraud or mislead consumers or the government. You may also unanimously find that the

defendant acted with the intent to defraud or mislead both consumers and the government, but only one of them is necessary to satisfy this element.

In the context of this statute, "intent to defraud or mislead" a consumer means the specific intent to deceive or cheat, ordinarily for the purpose of either causing some financial loss to another or bringing about some financial gain to one's self. "Intent to defraud or mislead" the government requires evidence that a defendant consciously sought to mislead a government agency.

JURY INSTRUCTION NO. 16

WHEN A DRUG IS MISBRANDED

The indictment has alleged that the products were misbranded in three distinct ways. The misbranding element is satisfied if you are convinced beyond a reasonable doubt that the products were misbranded in at least one of the three ways, but you must all agree on at least one particular way that the products were misbranded.

If a product meets the legal definition of a "drug," the product is misbranded unless it has certain labeling. "Labeling" means any written, printed, or graphic matter that appears on any product or on any of its containers or wrappers, or that accompanies the product. A "label" is that part of the labeling that is on the immediate container of the product. The requirements of what is required to be on the labeling may depend on whether the drug meets the legal definition of "prescription drug" or "new drug."

An article or item is a "drug" if it is intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans, or if it is intended to affect the structure or any function of the human body. Prescription drugs are those that, because of their toxicity or other potentiality for harmful effect, or the method of their use, or the collateral measures necessary to their use, are not safe for use except under the supervision of a practitioner licensed by law to administer such drugs. A new drug is one the composition of which is such that the drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof.

I. First Way

Section 352(f)(l) of Title 21 of the United States Code provides that a drug is misbranded if it does not have adequate directions for use. "Adequate directions for use" means "directions under which the layman can use a drug safely and for the purposes for which it is intended." Because prescription drugs by definition cannot be used safely by laypersons, all prescription drugs are misbranded unless they qualify for an exemption from the "adequate directions for use" requirement. In order to qualify for the exemption, each of the following must be met: (1) the label must bear an Rx symbol; and (2) the labeling on or within the drug's packaging must bear adequate information for its use, including indications, effects, dosages, routes, methods, and frequency and duration of administration, and any relevant hazards, contraindications, side effects, and precautions under which practitioners licensed to administer the drug can use the drug safely and for the purposes for which it is intended, including all purposes for which it is advertised or represented. Additionally, if the product qualifies as a "new drug," the labeling bearing such information must be the labeling authorized by the approved new drug application.

II. Second Way

A drug is also misbranded within the meaning of Title 21, United States Code, Section 352(f)(l) if its labeling fails to bear adequate warnings against use in pathological conditions where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for protection of users.

III. Third Way

A drug is misbranded within the meaning of Title 21, United States Code, Section 353(b)(4)(A)(1) if it is a prescription drug and the label of that drug fails to bear the symbol Rx only at any time prior to dispensing.